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10/537,378

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EXAMINER

COOK, LISA V

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/537,378 | Applicant(s) GUO ET AL. | |
| | Examiner LISA V. COOK | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

I. Applicant must select a single analyte. Please choose *one* of the following species:

- A. cell – claims 2 and 3
- B. a cellular organelle – claims 2 and 4
- C. a virus – claim 2
- D. a molecule – claims 2 and 5
- E. an aggregate – claim 2
- F. a hormone – claim 7
- G. a cancer marker – claim 7
- H. a steroid – claim 7
- I. a sterol – claim 7
- J. a pharmaceutical compound – claim 7
- K. a metabolite of a pharmaceutical compound – claim 7

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In addition if Applicant elects Group D above, Applicant must select either *one* of the following:

- a. As to the election of Group D, Applicant further elects an inorganic molecule reading on claims 2 and 5, or either
- b. As to the election of Group D, Applicant further elects an organic molecule reading on claims 2, 5 and 6.

II. Applicant must select a single sample type. Please choose *one* of the following species:

- L. mammalian sample is bovine – claims 8 and 9
- M. mammalian sample is goat – claims 8 and 9
- N. mammalian sample is sheep – claims 8 and 9
- O. mammalian sample is equine – claims 8 and 9
- P. mammalian sample is rabbit – claims 8 and 9
- Q. mammalian sample is guinea pig – claims 8 and 9
- R. mammalian sample is murine – claims 8 and 9
- S. mammalian sample is human – claims 8 and 9
- T. mammalian sample is feline – claims 8 and 9
- U. mammalian sample is monkey – claims 8 and 9
- V. mammalian sample is dog – claims 8 and 9
- W. clinical sample is serum or body fluid – claims 10, 11, and 13
- X. clinical sample is plasma or body fluid – claims 10, 11, and 13
- Y. clinical sample is whole blood or body fluid – claims 10, 11 and 13

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- Z. clinical sample is sputum or body fluid – claims 10, 11 and 13
- AA. clinical sample is cerebral spinal fluid or body fluid – claims 10, 11 and 13
- BB. clinical sample is amniotic fluid or body fluid – claims 10, 11 and 13
- CC. clinical sample is urine or body fluid – claims 10, 11 and 13
- DD. clinical sample is gastrointestinal contents - claims 10 and 11
- EE. clinical sample is hair – claims 10 and 11
- FF. clinical sample is saliva or body fluid – claims 10, 11 and 13
- GG. clinical sample is sweat or body fluid – claims 10, 11 and 13
- HH. clinical sample is gum scrapings – claims 10 and 11
- II. clinical sample is tissue from biopsies - claims 10 and 11
- JJ. clinical sample is a human clinical sample - claims 10 and 12
- KK. the sample is a body fluid sample – claim 13

III. Applicant must select a single reactant. Please choose *one* of the following species:

- LL. the reactant is a cell – claim 15
- MM. the reactant is a cellular organelle - claim 15
- NN. the reactant is a virus - claim 15
- OO. the reactant is a molecule – claim 15
- PP. the reactant is an aggregate – claim 15
- QQ. the reactant is an antibody – claim 16
- RR. the reactant is a nucleic acid – claim 17

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IV. Applicant must select a single assay format. Please choose *one* of the following species:

- SS. the assay format is a direct assay – claim 18
- TT. the assay format is a sandwich assay – claim 19
- UU. the assay format is a competition assay – claim 20
- VV. any of the various formats (i.e. ELISA, RIA, IHA, etc.) in claim 52 - claim 52

V. Applicant must select a single transition metal. Please choose *one* of the following species:

- WW. the transition metal complex is a ferrocene – claims 21 and 22
- XX. the transition metal complex is a metal porphyrin – claims 21 and 22
- YY. the transition metal complex is a metal polypyridine – claims 21 and 22
- ZZ. the transition metal complex is a metal poly-phenanthroline – claims 21 and 22
- AAA. the transition metal complex is a metal phthalocyanine – claims 21 and 22
- BBB. the transition metal is cobalt - claims 21 and 23
- CCC. the transition metal is nickel – claims 21 and 23
- DDD. the transition metal is osmium – claims 21 and 23
- EEE. the transition metal is iron – claims 21 and 23
- FFF. the transition metal is rhenium – claims 21 and 23
- GGG. the transition metal is chromium – claims 21 and 23
- HHH. the transition metal is ruthenium – claims 21 and 23
- III. the transition metal is ruthenium tris (2,2'-bipyridine) – claims 21, 24 and 25

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VI. Applicant must select a single oxide electrode. Please choose *one* of the following species:

JJJ. the oxide metal is selected from the group consisting of gold, platinum, silver, cobalt, nickel, and carbon – claims 26 and 27

KKK. the electrode is a metal oxide selecting from the group consisting of indium oxide, tin oxide, titanium oxide, zirconium oxide, tungsten oxide, zinc oxide, and iron oxide – claims 28, 29, 30 and 31

In addition if Applicant elects Group KKK above, Applicant must select either *one* of the following:

c. As to the election of Group KKK, Applicant must further elect a tin-doped indium oxide reading on claims 28, 29, 30, 31 and 32, or either

d. As to the election of Group KKK, Applicant must further elect a fluorine-doped tin oxide reading on claims 28, 29, 30, 31 and 33.

VII. Applicant must select a single reducing agent. Please choose *one* of the following species:

LLL. the reducing agent is an aqueous solution – claim 34

MMM. the reducing agent is an organic redox molecule – claims 35 and 42-44

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In addition if Applicant elects Group MMM above, Applicant must select either *one* of the following:

e. As to the election of Group MMM, Applicant must further elect an organic acid reading on claim 36,

f. As to the election of Group MMM, Applicant must further elect an organic base reading on claim 36 and 39-41,

g. As to the election of Group MMM, Applicant must further elect an organic ion reading on claims 36,

h. As to the election of Group MMM, Applicant must further elect an organic zwitterion reading on claims 36 and 45-51, or either

i. As to the election of Group MMM, Applicant must further elect an ionized organic acid/base reading on claims 42-22.

In addition if Applicant elects either Group e above, Applicant must select either *one* of the following:

j. As to the election of Group e, Applicant must elect either claim 37 reading on a carboxylic acid *or* claim 38 reading on a oxalic acid.

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2. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

3. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner: Each of the species are independent and distinct requiring separate search and considerations. The following claim(s) are generic: 1, 14 and 53-55.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species is directed to methods requiring independent and distinct reagent compositions, assay, formats, and/or electrodes.

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6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LISA V. COOK whose telephone number is (571)272-0816. The examiner can normally be reached on Monday - Friday 7:30am to 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lisa V. Cook
Patent Examiner
Art Unit: 1641
Remsen 3C-70
571-272-0816
3/29/08

/Lisa V. Cook/
Primary Examiner, Art Unit 1641